DEPARTMENT OF HEALTH & HUMAN SERVICES



SEP - 4 2001

Food and Drug Administration 2098 Gaither Road Rockville MD 20850

Mr. Raphael Wong President, Branan Medical Corporation 10015 Muirlands Road, Suite E Irvine, CA 92618

Re:

K012541

Trade/Device Name: Fastix[™] Drug Screen THC/COC Dipstick Test, Fastix[™] Drug

Screen THC/COC/MET Dipstick Test, FastixTM Drug Screen OPI/MET/THC/COC, Dipstick Test, and Fastix[™] Drug Screen

OPI/AMP/THC/COC Dipstick Test

Regulation Number: 21 CFR 862.3870, 862.3250, 862.3610, 862.3640, 862.3100

Regulatory Class: II

Product Code: LDJ, DIO, LAF, DKZ, DJG

Dated: August 1, 2001 Received: August 7, 2001

Dear Mr. Wong:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.

Director

Division of Clinical Laboratory Devices

Steven Dutman

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

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510(k) Numb	er (if known): <u>K00403</u> 4 <u>ドロソン5</u> 4
Device Name	Fastix TM Drug Screen THC/COC Dipstick Test
Indications Fo	
vitro screen carboxylic ac	Medical Corporation Fastix TM Drug Screen THC/COC Dipstick Test is an <i>in</i> test for the rapid detection of THC (11-nor-Δ ⁹ -Tetrahydrocannabinol-9-id) and Benzoylecgonine (cocaine metabolite) in human urine. The cutoff is are as follows:
THC COC	11-nor-Δ ⁹ -Tetrahydrocannabinol-9-carboxylic acid Benzoylecgonine 50 ng/ml 300 ng/ml
The test kit is only. It is no	used to obtain a visual, qualitative result and is intended for professional use tintended for over-the-counter sale to lay persons.
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(PLEASE DC	NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
	Concurrence of CDRH, Office of Device Evaluation (ODE)
	Conditioned of Contract Contra
Description I	Jse V OR Over-The-Counter Use
Prescription (Per 21 CFR	500
•	510(k) Number KU & J

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510(k) Numb	er (if known):	1004034 KO12	142		
Device Name	E Fastix TM	Drug Screen THC/C	OC/MET Dipstick T	est	
Indications Fo					
an in vitro sci	reen test for t	oration Fastix TM Dru the rapid detection of oncentrations are as f	THC, Cocame and	C/MET Dipstic I Methamphet	k Test is amine in
THC COC MET	11-nor-Δ ⁹ -Te Benzoylecgon D-Methamph)-carboxylic acid		ng/ml ng/ml ng/ml
The test kit is only. It is not	used to obtain	n a visual, qualitative over-the-counter sale	result and is intend to lay persons.	led for profess	ional use
(PLEASE DC NEEDED)	NOT WRITE	E BELOW THIS LINE	E-CONTINUE ON A	ANOTHER PA	GE IF
	Concu	rrence of CDRH, Off	ice of Device Evalu	uation (ODE)	
Prescription U		OR	Over-The	e-Counter Us	ə
(Per 21 CFR	801.109)	<i>)</i>	į	(Optional For	mat 1-2-96)
	(D)	Vision Sign-Off) vision of Clinical Laborator	y Devices		
		0(k) Number <u>K0125</u>	41		

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					Tago		
510(k) Number	(if known):	<u>K:004034</u>	K0125L	f (
Device Name:	_Fastix TM D	rug Screen	OPI/MET/TI	IC/COC Dip	ostick Test	· ·	
Indications For							
The Branan Me Test is an <i>in vit</i> and Cocaine in b	ro screen tes	t for the ra	apid detection	of Opiate, I	Methamph	COC D	ipstick THC,
						2000 n	a/mil

The test kit is used to obtain a visual, qualitative result and is intended for professional use only. It is not intended for over-the-counter sale to lay persons.

(PLEASE DO NOT WRITE NEEDED)	BELOV	V THIS LINE-	CONTINUE ON ANOTHER PAGE IF
Concur	rrence o	f CDRH, Offic	e of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)	1/	OR	Over-The-Counter Use (Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number_

					Page	4 of 4
510(k) Numb	er (if known):	K004034	+ K01254]		
• •	•		n OPI/AMP/T	•	stick Test	
		Di ug Sci cci	1 Of MARIANT	Herees 2.p		
Indications F						
Test is an in	vitro screen t	est for the r	stix TM Drug S rapid detection ncentrations a	n of Opiate, A	MP/THC/ Amphetam	COC Dipstick ine, THC and
OPI	Morphine					2000 ng/ml
AMP	Amphetamin	e	1110	llia aaid		1000 ng/ml 50 ng/ml
THC COC	11-nor-Δ'-Te Benzoylecgor	_	mabinol-9-car	boxyne acid		300 ng/ml
(PLEASE DC NEEDED)			HIS LINE-CO		_	
	Concu	rrence of CI	ORH, Office of	f Device Eval	uation (O	DE)
Prescription ((Per 21 CFR			OR	Over-Th	ne-Counte (Optiona	r Use I Format 1-2-96)
		(Division Sign- Division of Clin 510(k) Number	Off) nical Laboratory D	Pan Carry Devices		